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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,784	11/11/2003	Stephen F. Ridley	HMD-1	5220
22827	7590	09/22/2005	EXAMINER	
DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449			JAWORSKI, FRANCIS J	
			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/705,784	Applicant(s) RIDLEY ET AL.	
	Examiner Jaworski Francis J.	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/8/04, 9/13/04.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-55 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 11 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/8/04, 9/13/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 28 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Kopp et al (US4108165) which teaches a medical biopsy probe device and method of using same where the transducer housing includes an outer sterilizable sleeve portion 12 which covers the housing exterior as shown in Fig. 2 without impeding motion of the probe within the guide, and also shows transducer 34 and base 40 where the housing defines a probe guide opening with a sterile seal including sterilizable guide portion 14 and sterile probe guide 22, 26 which is removably attachable to the transducer housing and wherein portion 26 is received into the probe guide opening surrounding 14.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-4, 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kopp et al as argued above, and further in view of Dardel (US5341810) since the latter teaches that a sterile seal may include pliant thermoplastic sterile sleeve 16 where the embodiment includes a cylindrical transducer such as in Kopp et al and is adapted to extend the probe in the direction of the transmitted beam; and further teaches that the sterile containment may include separable portions.

Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kopp et al as applied to claims above, and further in view of Jingu (US4491137) since the latter teaches that where a sterile probe guide adaptor oriented perpendicular to the base of a probe device is used as in Kopp et al, a pliant thermoplastic sleeve 10 may be used to seal an ensonating linear ultrasound transducer from the patient.

Claims 7, 9-10, 22-24 and 55 are rejected under 35 USC 103(a) as being unpatentable over Kopp et al as applied to claims above, and further in view of Kelly, jr et al (US6475152) since the latter teaches that a sterile clamp may be used to secure the biopsy device to the ultrasound imaging array and further that when the combination of a sterile guide 32 and sterilizable seal 100 are used the linear array transducer itself may be arcuate in profile in order to conform to the body surface as shown in Fig. 4 therein.

Claims 8, 11, 25-27, 34 and 37-41 are rejected under 35 USC 103(a) as being unpatentable over Kopp et al in view of Kelly Jr. et al as applied to claims above, and further in view of Lin (US6261234) which teaches that in Fig. 3B when an arcuate transducer is used in this type of device the instrument path defined by the biopsy probe

channel opening is perpendicular to the tangent point of the arcuate profile base and parallel to the imaging plane while outside the area of the transducer(s) in order to engage tissue at the contact coupling point of the ultrasound ensonation which tracks the instrument.

Claims 12 – 21, 43-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kopp et al in view of Kelly, Jr et al as applied to claim 10 above, and further in view of Vilkomerson et al (US4249539) which teaches that the location and motion of the probe tip may be tracked in realtime so as to create a virtual display on a monitor by including a receive transducer within the instrument itself hence the technique is applicable across sterile barriers as in the former. Kelly Jr. et al otherwise teaches that the instrument probe path may be parallel to the plane of the sonogram. Vilkomerson et al otherwise notes that venous catheterization is an applicable use for this type of device, see col. 1 lines 31-37.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kopp et al in view of Dardell as applied to claim 29 above, and further in view of Carroll et al (US5119818) which teaches that a sterile seal 200 of fig. 3 might include a base portion as well as a sleeve since this protects both the sterile needle as well as the tissue contact point from the unsterilized ultrasound instrument.

Claims 35 – 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kopp et al in view of Kelly Jr et al and Lin as applied to claim 34 above, and further in view of Jingu since the latter teaches that the biopsy path when involving an


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ultrasound array transducer may pass through the area defined by the ultrasound transducer.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738

FJJ:fjj

09202005


Francis J. Jaworski
Primary Examiner